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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,031	12/11/2003	Robert Zaczek	BMS-PH-7048-A(C)	8984

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,031	ZACZEK ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005 and 03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-18,20-22,36-49,54-65 and 70-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-18,20-22,36-49,54-65 and 70-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/8/05 wherein the specification was amended; claims 11, 12, 19, 23-35, 50-53, and 66-69 were canceled; and claims 1, 6, 13, 14, 17, 18, 20-22, 36-49, 54-59, 65, 70, 71, and 77 are amended.

Note: Claims 1-10, 13-18, 20-22, 36-49, 54-65, and 70-77 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election of Group V in the reply filed on 4/8/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction requirement is still deemed proper and is made FINAL.

OBVIOUSNESS-TYPE DOUBLE PATENTING

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 6, 17, 18, 20, 22, 54, and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,878,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a neurological disease using an amyloid secretase inhibitor. The claims differ in that in the patented invention the inhibitor is identified whereas in the instant invention one has to first screen a series of macromolecules to obtain an inhibitor, then use the inhibitor for treating a neurological disease. It would have been obvious to one of ordinary skill in the art that the two inventions overlap because one would recognize that both inventions are directed to secretase inhibitors and that those inhibitors are used in the same methods, treating neurological diseases.

5. Claims 1-6, 9, 10, 13-18, 20, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 15-23, 28-30, 50, and 51of U.S. Patent No. 6,331,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of screening for amyloid inhibitors. The claims differ in that those of the patented invention are not limited to secretase inhibitors. Thus, a skilled practitioner would recognize that the claims of the patented invention encompass those of the instant invention since the inhibitors of the instant invention are within the scope of the patented invention and both sets of inhibitors were determined from a method of screening.

6. Claims 1-6 and 59-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-7, 29, 34-42, 46-50, and 52 of copending Application No. 11/018,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of screening for amyloid inhibitors and imaging. The claims differ in that in the instant invention one first screens for the inhibitor and uses that specific inhibitor in various methods wherein in 11/018,331, one performs diagnostic imaging in a compound (i.e., claim 34) and determines if the imaged compound exhibits activity as an inhibitor in a method of screening (i.e., claim 40).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 FIRST PARAGRAPH REJECTIONS

New Matter

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6-10, 41-49, 54-65, and 70-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Formula I (e.g., claim 6, lines 3, 6, 21, 28, 54, 57, and 68) has been amended to replace '**$C_6 - C_{10}$ aryl**' with '**aryl**' which is inconsistent with the specification and is new matter because the phrase '**aryl**' encompasses aryls that were not set forth in the originally filed disclosure.

Enablement

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 17 is are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Alzheimer's disease, does not reasonably provide enablement for all degenerative neurological disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

Claim 17 is directed to a method of treating degenerative neurological disorders using a be amyloid inhibitor.

(2) State of the prior art

The references do not indicate which specific diseases or classes of diseases that are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 17 encompasses a vast number of neurological disorders. Applicant's specification does not enable the public to use the amyloid inhibitors with such a vast number of neurological disorders.

(4) Level of predictability in the art

The art pertaining to the neurological disorders highly unpredictable. Determining the various types of neurological disorders or class of disorders that will be inhibitor by beta amyloid requires various experimental procedures and without guidance that is applicable to all neurological disorders, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 17 encompasses a vast number of neurological disorders. Applicant's limited guidance does not enable the public to use such a numerous disorders in combination with a beta amyloid inhibitor. There is no directional guidance for the various neurological disorders that will be inhibited by beta amyloid compounds, except Alzheimer's disease which is set forth in Applicant's specification. Hence, there is no enablement for all possible neurological disorders.

(6) Existence of working examples

Independent claim 17 encompasses a vast number of disorders. Applicant's limited working examples do not enable the public to use such amyloid inhibitors in for numerous neurological disorders. While Applicant's claims encompass a plethora of

neurological disorders, the specification provides only one disorder, Alzheimer's disease.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible neurological disorders known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTIONS

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 6, 14, 55, 57, 58, 64, 68, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, last line: The claim as written is ambiguous because of the phrase 'R20 is H or C1 – C6 alkyl'. In particular, the variable 'R20' is not present in the structures or other variable definitions set forth in the claim. Did Applicant intend to delete the last line?

Claim 14: The claim as written is ambiguous because of the phrase 'or any fragment or derivative thereof'. In particular, for the terms 'any fragment' and 'derivative', it is unclear what portion of the parent structure remains because a derivative or fragment of the secretase may not be functional and thus, the derivative/fragment would not be of use with the instant invention.

Claims 55, 57, and 58: The claim as written is ambiguous because of the phrase 'fragment thereof'. In particular, it is unclear what portion of the parent structure remains because a fragment of the secretase may not be function and thus, the fragment would not be of use with the instant invention.

Claims 64 and 76: The claims as written are ambiguous because they are directed to any compound disclosed in or within the scope of compounds in various references. In particular, the claims are ambiguous because the second paragraph of 35 USC 112 requires that the claims particularly point out the subject matter that Applicant regards as the invention. Thus, a claim referring to other compounds encompassed by or within the scope of various documents is improper. Furthermore, it is noted that the documents have been improperly incorporated.

COMMENTS/NOTES

13. It should be noted that reference numbers 66, 68, and 72 on the information disclosure statement filed 9/3/04 have been lined through because the documents were not present in the application during examination. If Applicant would like the documents to be considered, it is respectfully suggested that Applicant submit the documents with the next correspondence to the Examiner.

14. It should be noted that the closest art is Applicant's own work that is cited in the double patenting rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of screening as set forth in independent claim 1 wherein a tagged inhibitor of beta amyloid production with at least one secretase is tagged (contains a radiolabel).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

June 24, 2005